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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09 575,580 | 05 22 2000 | Frank McKeon | HMSU-P01 048 | 1156 |

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KAM, CHH MIN

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1653

DATE MAILED: 11/29/2002

27

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/575,580 | MCKEON ET AL. |
| | Examiner Chih-Min Kam | Art Unit 1653 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 09 September 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-3 and 5-12 is/are pending in the application.

4a) Of the above claim(s) 1,3 and 5-12 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 2 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a) (d) or (f).

a) All b) Some * c) None of:

1 Certified copies of the priority documents have been received.

2 Certified copies of the priority documents have been received in Application No. _____.

3 Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

Attachments

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10,26.

4) Interview Summary (PTO-411 and/or 412)

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

DETAILED ACTION

Oath/Declaration

1. It is noted that on 5 March 2001 applicant's representative filed a petition under 37 C. F. R. 1.47(a). Subsequent to the mailing of this Office Action, the application will be forwarded to the Office of Petition for a decision on the petition. Applicant/Applicant's Representative will be notified of the decision under separate cover.

Election/Restrictions

2. Applicant's election with traverse of Group I, claims 1-3, and SEQ ID NO:2 in Paper No. 24 is acknowledged. In the Response to Restriction Requirement (Paper No. 4), claim 4 has been cancelled, and new claims 8-12 have been added. However, claims 8-12, drawn to a method for identifying a compound that modulates the activity or level of a Csp protein by contacting a cell with a test compound and determining the level or activity of the Csp protein using the antibody specifically binding to the Csp protein, will be in Group VI, classified in class 530, subclasses 350 and 387.1; claims 8 and 12, drawn to a method for identifying a compound that modulates the activity or level of a Csp protein by contacting a cell with a test compound and determining the level of Csp RNA, will be in Group VII, class 536, subclass 23.1. The traversal is on the ground(s) that the search including all the groups can be made without additional burden. This is not found persuasive because applicant's response has not demonstrated no undue burden. Restriction is proper when two or more claimed inventions are either independent **or** distinct. See MPEP 803. Furthermore, coexamination of each of the

530, subclasses 350, and class 514, subclass 12, as well as additional amino acid sequences. Therefore, coexamination of each of these inventions would require a serious additional burden of search.

The restriction groups have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the invention is not coextensive particularly with regard to the literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or make obvious any of the other group. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exist.

Claims 1 and 3 contain non-elected sequences and are withdrawn from further consideration. The requirement is still deemed proper and is therefore made FINAL.

Sequence Listing

3. The amendment filed January 18, 2002 regarding the sequence listing is acknowledged, and CRF has been entered.

Informalities

4. The disclosure is objected to because of the following informalities:

The specification indicates a nucleic acid having ATCC Deposit No. ____ (e.g., page 27, line 30); however, "ATCC Deposit No" is not provided ("ATCC" is a registered Trademark). If

applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the vector has been deposited under the Budapest Treaty and that the vector will be irrevocably and without restriction or condition be released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. See 37 CFR 1.808. Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample or for the enforceable life of the patent, whichever is longer. See 37 CFR 1.806. If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met. Amendment of the specification to disclose the date of deposit and the complete name and address of the depository is required. If the deposit was made after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a position to corroborate that the plasmid described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed. Applicant's attention is directed to *In re Lundak*, 773 F.2d. 1216, 227 USPO 90 (CAFC 1985) and 37 CFR 1.801-1.809. For further information concerning deposit

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claim 2 is rejected under 35 U.S.C. 102(e) as being anticipated by Palleja *et al.* (U. S. Patent 5,869,318).

Palleja *et al.* teach a nucleic acid molecule DSCR1 (SEQ ID NO:1) and an antisense synthetic oligonucleotide of 40 base pair (SEQ ID NO:9) which is complementary to bases 136 to 97 of the human cDNA sequence of DSCR1, and studies in situ hybridization is carried out with the oligonucleotide under a hybridization condition containing 0.6 M NaCl, 1X Denhardt's solution, 10 mM Tris-HCl pH 7.5, and a washing condition of 1 x SSC at 52 °C (column 9, lines 30-65; claim 2). Sequence search indicates that DSCR1 has 66.7% sequence homology with SEQ ID NO:2 of the instant application (See attached sequence match), therefore claim 2 is

anticipatory. This concludes the search.

Conclusion

6. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

November 25, 2002

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600